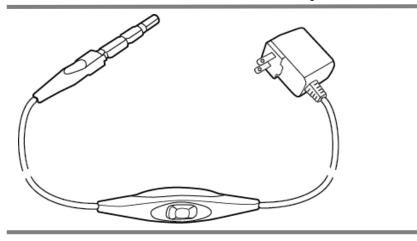
# Welch Allyn<sup>®</sup> KleenSpec 78900 and 78950 Corded Illumination System



Quick start guide

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This manual applies to **REF** 901070 VAGINAL SPECULUM LIGHTING SYSTEM

REQUIATORY Affairs Representative
Welch Allyn Limited
Navan Business Park
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## **Quick start guide**

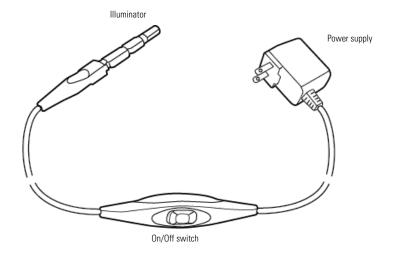
## KleenSpec Corded Illumination System

The KleenSpec Corded Illumination System is designed to work with the following Welch Allyn specula: 58000S, 58001S, 58004S, 590XS, 59000, 59001, 59004, 59005, and 59006 for gynecological and obstetric procedures.

The power supply provides power from the hospital-grade wall outlet to the illuminator assembly which houses the lamp. This provides illumination to the specula. This device is intended for use only with Welch Allyn-appropriate accessories.

This product is for use with the Welch Allyn KleenSpec Vaginal Specula only. Do not use the illuminator for any other use. Lamp is hot and can cause a burn if used outside of the vaginal specula.

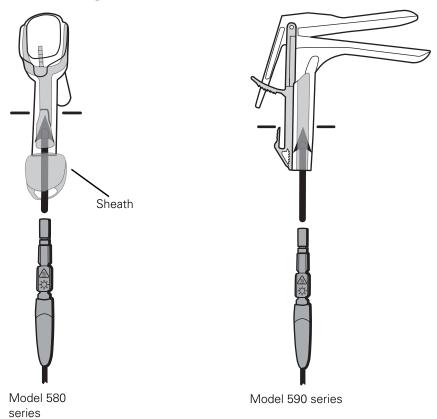
The illuminator slides into the appropriate Welch Allyn KleenSpec Vaginal Specula listed above. Verify all connections are made prior to applying power with the on/ off switch.



Note

For a complete copy of the directions for use, visit www.welchallyn.com. For a printed copy of the directions for use, contact contact Welch Allyn Technical Support: (www.welchallyn.com/support), or visit www.welchallyn.com/about/company/locations.htm

## **Inserting the Illuminator**



## Classification

Class II, Type BF Applied Part Ordinary Equipment
Clean and disinfect as directed in Cleaning Section Non-continuous Operation

## **Symbol Descriptions**

<u> </u>	Warning	welchallyn.com	Consult Directions for Use
Ŵ	Caution	•	Lamp On
	Caution, high temperatures		Lamp Off
-	Caution, high intensity light	<b>†</b>	Type BF Applied Part
	Double Insulation	===	Direct Current
IPX7	Illuminator is protected against the effects of temporary immersion in water (and the solutions described in this manual)	IPX0	Power supply - Not protected from the ingress of water.

## **Warnings and Cautions**



WARNING: To avoid eye injury, do not look into the beam.



WARNING: Lamp is harmful to skin if touched. Allow lamp to cool for 5 minutes before replacing. Lamp generates heat and should remain off until just prior to and immediately after use. Do not place illuminator onto a flammable surface if lamp is illuminated.



WARNING: Disconnect power supply from outlet prior to any maintenance.



WARNING: This product is for use with the Welch Allyn KleenSpec Vaginal Specula only. Do not use the illuminator for any other use. Lamp is hot and can cause a burn if used outside of the vaginal specula.



WARNING: KleenSpec Corded Illumination System is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. An explosion may result.



WARNING: The lamp is hot and can cause burns if used outside of the vaginal specula.



CAUTION: Properly secure all cords and cables to minimize trip hazards.



CAUTION: Use only the cleaning methods and disinfection solutions/methods described in this manual. Clean the device prior to disinfection.



CAUTION: The Illuminator is a biohazard after use. Follow good hospital practices and the instructions for cleaning and disinfection of the illuminator within this manual prior to the next usage.



CAUTION: Ensure lamp is installed and fully seated in illuminator throughout cleaning and disinfection process. The illuminator assembly is immersible (IPX7) provided the lamp is properly installed.



CAUTION: This device complies with current required standards for electromagnetic interference, and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.



CAUTION: The illuminator cable is capable of temporary immersion to a depth of 0.15 to 1 meter, at ambient pressure, at room and fluid temperatures of 22° C to 43° C. The power supply is not. Do not immerse the power supply.

U.S. Federal Law restricts this device to sale by or on the order of a physician.

To remove all power from the Vaginal Illumination System, unplug the external power supply from the wall outlet.

There are no user-serviceable parts inside the device except the lamp. Contact Welch Allyn Technical Support: www.welchallyn.com/support.

## **Cleaning and Disinfecting**

		KleenSpec Corded Illuminator	Power supply
	CaviWipe (Wipe)	Yes	Yes
Cleaning	Enzol (Soak)	Yes	No*
	Metrizyme (Soak)	Yes	No*
Disinfecting	Caviwipe	Intermediate Level	Intermediate Level

<sup>\*</sup> Do not immerse the power supply plug. Follow instructions per this manual.

#### Cleaning

#### Wipe

#### KleenSpec Corded Illumination System

Refer to Cleaning Table to identify the appropriate cleaning product.

1. Disconnect the power supply from the wall outlet.



CAUTION: Lamp must remain installed during all cleaning and disinfecting processes.

- 2. Follow the disinfecting wipe manufacturer's instruction and wipe cord or illuminator completely to remove any residue.
- This process is a rough clean only. Refer to disinfection for further processing.

#### Soak

Refer to Cleaning Table to identify the appropriate cleaning product.

#### **KleenSpec Corded Illuminator**

1. Disconnect the power supply from the wall outlet.



CAUTION: Lamp must remain installed during all cleaning and disinfecting processes.

- Follow the cleaning solution manufacturer's instructions and soak the illuminator as instructed. Solution temperature is 22° C to 43° C. Make sure to keep the power supply out of the soak solution. Do not immerse the power supply.
- 3. Scrub any area of visible debris with a soft brush and thoroughly rinse the illuminator with 22° C to 43° C tap water to remove the cleaning solution. Do not rinse the power supply; wipe only.

- 4. Rough dry the illuminator.
- 5. The illuminator is now ready for disinfection.

#### Disinfecting

Refer to the Cleaning Table to identify the appropriate disinfection method/product for the illuminator and power supply.

#### Illuminator

- 1. Clean or disinfect as described in the table above.
- 2. Follow the disinfecting wipe manufacturer's disinfection instructions.
- Thoroughly rinse illuminator with 22° C to 43° C tap water to remove disinfectant.
- 4. Allow to dry.

#### **Power supply**

#### DO NOT IMMERSE THE POWER SUPPLY.

- 1. Clean or disinfect as described in the table above.
- Follow the disinfecting wipe manufacturer's disinfection instructions on the cord only.
- 3. Thoroughly rinse the **cord only** with 22° C to 43° C tap water to remove disinfectant. Do not immerse the power supply.
- Allow to dry.

### **Disposal**

There are no harmful materials associated with the Illumination System.

Device is considered a biohazard after use. Follow good hospital practices and local ordinances in the disposal of the illuminator.

There are no risks associated with the disposal of this device after its useful life if it is cleaned and/or disinfected per the instructions in this manual.

## **Approvals**

CERTIFIED TO: CAN/CSA STD C22.2 NO. 601.1 CONFORMS TO: IEC 60601-1, IEC60601-1-2



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